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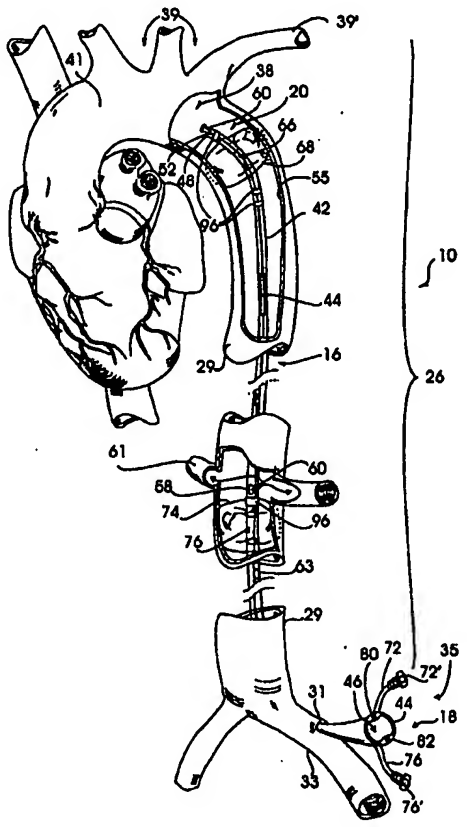
(54) Title: MAIN STAGE CATHETERIZATION INSTRUMENT

(57) Abstract

The present invention discloses a main stage catheter instrument which serves as the primary catheterization access and arterial perfusion cannula for establishing cardiopulmonary bypass with selective perfusion and differential flow management of the cardiovascular, cardioneural and corporeal sub–circulations of a patient. The main stage catheter has a catheter shaft with a first occlusion member for occluding the thoracic descending aorta and an optional second occlusion member for occluding the abdominal descending aorta. A perfusion lumen in the main stage catheter supplies oxygenated blood to the aorta through distal, medial and proximal perfusion ports. Optionally, a second stage catheter inserted through the main stage catheter may be used to occlude the ascending aorta and to deliver a cardioplegic agent to the coronary arteries. The main stage catheter is coupled to a cardiopulmonary bypass system and a venous drainage catheter to establish partial or full cardiopulmonary bypass with elective cardioplegic arrest.



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MAIN STAGE CATHETERIZATION INSTRUMENT

CROSS REFERENCE TO OTHER APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application serial number 60/060,127, filed September 26, 1997, the specification of which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

This invention relates generally to devices and methods for supporting partial or full cardiopulmonary bypass of a patient undergoing surgical interventions of the beating, partially arrested or fully arrested heart. More specifically, the invention relates to devices and methods for selective management of cardiovascular, cardioneural and corporeal cardiopulmonary bypass support of a patient undergoing any of a variety of routine and high-risk cardiovascular and cardioneural surgical interventions.

BACKGROUND OF THE INVENTION

Partial or full cardiopulmonary bypass (hereafter "CPB") support is needed for medical procedures requiring general anesthesia where lung function is to be arrested during routine and high-risk cardiovascular, cardioneural and other surgical interventions including beating, fully arrested or partially arrested cardiac procedures, to maintain cardiovascular, cardioneural and corporeal support of the respective heart, cerebral and corporeal organ systems. Such surgical interventions include treatment of aneurysms, congenital valve disease, and coronary artery disease. Cardiac interventions such as angioplasty, atherectomy, thrombectomy, coronary bypass grafting, heart valve repair or replacement are some of the other procedures that can be performed. Many of these procedures, have in the past required direct access to the thoracic cavity and have been performed using severely traumatizing open-chest surgical techniques.

In procedures where the heart is to be fully or partially arrested, it is preferred that the heart and coronary vasculature be isolated from the rest of the cardiovascular system. Isolation allows antegrade or retrograde perfusion of cooled, oxygenated blood or crystalloid cardioplegia to the heart blood vessels to maintain arrest while preventing dispersion of cardioplegia to the rest of the body. Also, the heart chambers may then be vented for decompression and to create a bloodless surgical field for intracardiac interventions. For rapid cooling and arrest of the myocardium in open-chest procedures, direct topical hypothermia application of iced saline into the thoracic space is performed adjunctively. While the heart is arrested, oxygenated blood may be perfused to the rest of the body to maintain cerebral and corporeal support without perfusion to the heart blood vessels which could resuscitate the partially or fully arrested heart, and obscure the surgical field with blood before completion of the surgical intervention.

Currently, CPB is accomplished by withdrawing deoxygenated blood from a venous blood vessel of a patient, such as the vena cava, through a catheter which is connected to a pump. The pump circulates the withdrawn blood through a blood oxygenator, heat exchanger and filter apparatus and then perfuses the oxygenated and temperature controlled blood and other fluids through an aortic perfusion catheter inserted into the aorta of the patient. Isolation of the heart and its blood vessels is accomplished by segmenting the aorta downstream from the coronary ostia and upstream from the brachiocephalic trunk either with an externally applied mechanical cross clamp or by a inflation of an aortic balloon catheter such as that described in U.S. Patent Nos. 5,308,320 and 5,383,854 to Safar et al. The entire disclosures of both patents are hereby incorporated by reference. Application of the cross-clamp generally requires a thoracotomy to gain easy access to and for dissection of the exterior of the aorta. The aortic perfusion catheter is inserted into the aortic lumen downstream from the clamp or aortic balloon catheter whereby oxygenated blood is perfused to the arch vessels and the rest of the body.

The Safar patents teach a minimally-invasive technique for peripheral introduction of the aortic balloon catheter to eliminate the need for a thoracotomy to establish CPB to facilitate intravascular surgical interventions. Additionally, Safar teaches a minimally-invasive, peripherally

introduced device and method for selective differential perfusion which are capable of segmenting the circulatory system of a patient such that the cardiovascular sub-circulation may be isolated from the cardioneural sub-circulation which, in turn, may be both isolated from the corporeal or rest of the body circulation. This device and method makes it possible to independently communicate different composition fluids, at different temperatures and flow rates to or from each of the sub-circulations. Using this capability, cardioplegia can be perfused to the heart while the brain and the rest of the body, or corporeal organ systems, are respectively and differentially perfused with independently variable fluid compositions, temperatures and flow rates. This is useful for establishing controllable hypothermia of a patient undergoing CPB. Cooling of the body reduces its demand for oxygen which, in turn lowers the demand for oxygenated blood flow. Therefore, the diameters of the catheters needed to provide such flow may also be reduced at lower temperatures.

To minimize or reduce problems during CPB, close management of the flow rates, compositions and temperatures of the fluid mixtures perfused to the various sub-circulations is required. This is especially important for the cardiovascular and cardioneural sub-circulations which are known to be more sensitive to undesirable conditions than other parts of the body.

Additionally, rapid, guided introduction, manipulation and removal of various interventional surgical instruments must be carefully performed to minimize the potential for injury to the patient, time required to accomplish the surgical procedure and so as to avoid any disruption of the CPB sub-circulatory flows.

Therefore, new primary support, main stage instruments and methods are needed which facilitate managed cardiovascular and cardioneural support during CPB and peripheral intraluminal, minimally invasive, percutaneous access to selected cardiac, cardiovascular and cardioneural locations for performing various surgical interventions without the need for severely traumatic procedures such as a thoracotomy. Such new main stage instruments and methods are needed to reduce the risk of serious complications from infection, embolic debris and tissue trauma, which, in turn, minimizes recovery time and lowers medical costs. These main stage instruments must be

optimally configured for closely managed CPB support of various sub-circulatory vascular beds and to have minimized external diameters while also having internal diameters large enough to allow introduction of secondary interventional instruments through or with the main stage instruments so as to minimize the number and severity of incisions needed and the time required for guided introduction, manipulation and removal of the interventional instruments.

SUMMARY OF THE INVENTION

The invention relates to a precision engineered main stage catheter instrument which serves as the primary catheterization access and support instrument providing the surgeon with the ability to establish CPB and selective, differential management of the cardiovascular, cardioneural and corporeal sub-circulations of a patient. The main stage instrument is optimally configured for closely managed lower perfusion flow rates for cardioneural, cardiovascular and corporeal organ support and which accommodates the rapid, guided introduction, with or without guide wires, manipulation and removal or exchange of various secondary, tertiary and quaternary surgical and perfusion instruments enabling a surgeon to more efficiently accomplish either routine or high-risk interventions, or a mix of the two.

The various additional precision engineered instrument stages to be used with the main stage instrument are designed with smaller outer diameters for compatibility with minimally-invasive surgical procedures. The second, third and fourth stage instruments usually will have maximum outer dimensions capable of introduction through the lumens, channels and/or passageways of the main, secondary and third stage instruments, respectively. Such minimally-invasive procedures are increasingly desirable for their associated lowered costs resulting from the reduced trauma to and faster healing of tissue, the decreased pain to the patient, the reduced adverse side-effects and post-operative complications, the reduced risk of infections and the resulting shorter stay in the hospital. For use with most normal adult or pediatric patients, the main stage catheterization instrument may be selected to include multiple fluid communication lumens for selective perfusion of different composition or temperature fluids. More than two central or smaller secondary lumens can be

incorporated in the main, second and other stage catheters as may be required by the needed surgical interventions. All such catheter lumens may be configured to perfuse or aspirate fluid and blood. The lumens can also be configured to, while fluid is being perfused therethrough, introduce, advance, manipulate and exchange and remove the adjunctive secondary, tertiary, and quaternary stage instruments. Alternatively, the main stage instrument may be configured for use with other instruments to be introduced alongside the main stage instrument.

Flow controlling valve-type and balloon functions are accomplished on various embodiments of the main stage instrument with a wide array of devices which may be disposed adjacent to the ports and operative remotely or locally to control or stop flow through the respective ports, lumens or past the exterior of the main stage instrument shaft. The main stage instrument is adapted for use with CPB equipment which includes pumps, debubblers, filters, oxygenators, heat exchangers, blood component reservoirs and medicinal reservoirs. Various positive or negative pressure heads can be maintained by the pumps to vary the respective flow rates through the fluid communication lumens of the instruments and thereby to and from the ports in fluid communication with such lumens. Although the main stage catheter system is described below in the context of left heart or arterial applications, it is also intended for and entirely compatible for use in right heart or venous surgical support and interventions.

Accordingly, it is an object of the present invention to provide a precision engineered, primary or main stage support instrument and method capable of establishing minimally invasive, full or partial CPB support through peripheral blood vessels and which can closely, but independently or collectively manage the cardiovascular, cardioneural and corporeal support functions and which is also capable of supporting various surgical interventions, all without the need for gross, high-trauma incisions such as a thoracotomy or median sternotomy.

It is a further object of the invention to provide a main stage instrument and method which can facilitate minimally invasive, peripheral access to a secondary instrument capable of isolating the cardiac vasculature and arresting the heart, without the need for additional incisions and which

is, in any embodiment or variation, compatible for use with either a beating, partially arrested or fully arrested heart.

Another object of the present invention is to facilitate minimally invasive, peripheral access for the guided introduction, with or without guide wires, of various secondary endovascular surgical instruments into the vasculature for performing a variety of surgical interventions and for the introduction of a variety of tertiary and quaternary instruments through or alongside the main or secondary instruments for interventional or sensing purposes.

These and other objects and advantages of the present invention will become more apparent from the following detailed description of the invention when considered in conjunction the accompanying exemplary drawings. Such drawings are provided for purposes of illustration only and are not intended limit the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Referring now to the drawings, wherein like reference numerals across the several views refer to identical or corresponding parts,

FIG. 1 is a perspective view of an exemplary embodiment of the precision engineered main stage catheter instrument of the present invention;

FIGS. 2a, 2b, 2c and 2d, are rotated partial views, in enlarged scale of a variation of the exemplary embodiment; and

FIG. 3 is a perspective view of precision engineered second, third and/or fourth stage catheter instruments embodying the present invention.

The objects and advantages of the present invention will become more apparent from the following detailed description of the invention when considered in conjunction with these accompanying exemplary drawings. Such drawings are provided for purposes of illustration only and are not intended to limit the scope of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The precision engineered main stage catheterization instrument of the present invention is compatible for use with other precision engineered second, third and fourth stage catheters and instruments that may be advanced into the patient's vasculature either through a central lumen or a surgical instrument passageway of the main stage catheter in a staged arrangement as described in more detail below. Alternatively, the adjunctive secondary, tertiary and quaternary instrument(s) may be introduced separately from the main stage catheter in parallel through the main stage incision site or through a separate vascular access incision. The secondary, tertiary and/or quaternary stage instruments are intended to be introduced through or utilized with the main, secondary and tertiary stage instruments, respectively. Although the exemplary embodiment described herein is adapted for a femoral arterial approach to cardiovascular and cardioneural cardiopulmonary (hereafter "CPB") and interventions, other comparable arterial and venous vessels are indicated for intracardiac right heart, left heart or other interventions directed to the arterial or venous vasculature. The precision engineered main stage catheterization instrument, as well as the secondary, tertiary and quaternary instruments, are all compatible for use with standard blood vessel introduction imaging and monitoring methods including fluoroscopy, angioscopy, endoscopy and thoracoscopy, and ultrasonic methods including transesophageal echocardiography as well as other newer techniques. Such newer techniques include, among other methods, tactile feedback signaling bumper devices which are designed to prevent further advancement during introduction of the instruments once the precise insertion position at a selected location of a blood vessel or heart chamber, or elsewhere in another cavity of the body, has been reached. Such a bumper device is described in copending, co-owned U.S. Provisional Patent Applications serial numbers 60/060,158, filed 09/26/97, and 60/073,681, filed 02/04/98, which, together with their corresponding utility patent application, are hereby incorporated by reference in their entirety.

Referring now to FIG. 1, an exemplary embodiment of the precision engineered main stage catheter instrument 10 of the present invention is shown. The instrument 10 incorporates an elongated, tubular catheter device 16 having an external proximal end 18 and an internal distal end

20 and is configured to be percutaneously introduced through a peripheral arterial incision site using well-known Seldinger needle-guide wire insertion techniques. Once introduced, the main stage instrument may serve as a guiding device for the introduction of other instruments into the vasculature, with or without additional guide wires. FIG. 1 shows the instrument 10 deployed in an operative position 26 within the descending aorta 29 of a patient through an incision 31 in the femoral artery 33. The elongated catheter device 16 is configured to extend between an external location 35 and a selected location 38 in the descending aorta 29 downstream from the blood vessels of the aortic arch 41. The catheter device 16 is formed with a catheter shaft 42 having either a single lumen or multilumen construction and is preferably extruded of a non-thrombogenic, non-hemolytic, flexible, optically-clear thermoplastic material or a thermoplastic elastomer. Optical clarity is preferred, although it is not required for all applications, for such embodiments adapted for arterial use so that the user may visually confirm the absence of bubbles in the perfusate passing through the internal fluid communication lumens. Suitable materials include, but are not limited to, polyvinyl chloride, polyurethane, polyethylene, polypropylene, polyamides (nylons), and alloys or copolymers thereof, as well as braided, coiled or counterwound wire or filament reinforced composite materials.

In the exemplary embodiment of FIG. 1, a single fluid communication lumen 44 extends from a proximal port 46 formed in the proximal end 18 to the distal end 20 where it opens to an upstream or distal port 48. The distal end 20 has either a simple beveled or rounded distal edge 52 with an opening therethrough forming the distal port 48 for retrograde fluid communication with the upstream brain and heart arteries and antegrade fluid communication with the blood vessel lumen 55 for perfusion to the downstream corporeal arteries. The distal end 20 may, in a variation of the exemplary embodiment, also include additional side ports or a flow diffuser to reduce jetting or blockage of suction when a fluid, such as blood, is infused or aspirated through the fluid communication lumen 44. An additional medial fluid communication port 58 is formed in the shaft 42 which is disposed to, when the instrument 10 is in the operative position 26, communicate fluid from the lumen 44 to the corporeal arteries, including for example the renal arteries 61. The medial port 58, as well as any other later-described ports, may also incorporate the anti-jetting or flow diffuser features described above for the distal port 48. In a variation of the exemplary embodiment,

the maximum size of the medial port 58 is adjusted to be smaller than the maximum size of the distal port 48 so as to ensure that, for a given fluid pressure in the fluid communication lumen 44, more fluid is perfused through the distal port 48 than is perfused through the medial port 58. The relative sizing of the ports also takes into account the pressure head energy loss of the fluid which travels further through the lumen 44 to reach the distal port 48. This relative sizing of the ports establishes a preferential maximum rate of fluid flow to the upstream aortic arch region of the aortic lumen 55 relative to the renal arteries 61 such that when the aortic lumen 55 is further segmented as described below, the cardioneural and cardiovascular sub-circulations receive more oxygenated blood than the renal arteries 61. This is preferred since, during hypothermia as described in more detail below, the kidneys and other corporeal or visceral organs require less blood flow than the brain and the heart while the extremities of the body require even less blood flow. A downstream port 64 may be optionally included which is formed in the shaft 42 between the medial port and the external end 18 which is sized to be smaller than both the medial port 58 and the distal port 48 to preferentially perfuse fluid at a lower flow rate to corporeal blood vessels downstream from the renal arteries 61. The above-described anti-jetting or diffuser type ports may also be formed in place of the downstream port 64. Also, varying the number of openings for the respective distal, medial and/or downstream ports can be used to adjust relative rates of flow through the respective ports by changing the effective cross-sectional exit plane area of the respective ports.

The proximal port 46 of the proximal end 18 is adapted for connecting the fluid communication lumen 44 to a cardiopulmonary bypass (hereafter "CPB") reversible pump or other source of vacuum or perfusate (not shown) using standard polycarbonate or rigid polyurethane barb connectors or other connectors, such as a standard luer fitting (not shown). The reversible pump will have an adjustable flow rate and may be able to maintain either a constant positive or negative pressure and/or a constant volumetric flow rate. The proximal end 18 may also incorporate a sliding hemostasis valve or valves (not shown) for each lumen, channel and/or instrument passageway, including the fluid communication lumen 44, for minimizing loss of blood and fluid from the proximal end during introduction, advancement or removal of secondary interventional instruments

to the selected location 38 through either the fluid communication lumen 44 or other lumens, channels or passageways which may be incorporated into variations of the exemplary embodiment.

The catheter device shaft 42 has a length sufficient to reach from the external, peripheral access point where it is inserted to the selected location 38 of the descending aorta 55 of the patient. For femoral artery introduction, as illustrated in FIG. 1, to a selected location 38 close to the aortic arch 41, the length is preferably approximately 80-120 centimeters for use in normal adult human anatomies depending on the corresponding size and configuration of the adult or pediatric patient's vascular anatomy. The length is selected to be as short as practical so as to minimize the pressure head energy loss and the hemolytic effects to the fluid and blood mixture passing through the fluid communication lumen 44. Shorter or longer lengths may be used for pediatric (including infants) and larger adult patients, respectively. The shaft 42 is preshaped to have a curvature for optimum introduction compatibility with the selected insertion procedure such that the shaft 42 may be maintained in a somewhat central disposition within the blood vessel lumen, relative to the natural anatomical centerline or axis, once the instrument 10 has been fully introduced. For purposes of illustration, the catheter shaft 42 of FIG. 1 has a generally inverted "J"-shaped preformed curvature to follow the natural anatomical curvature of the descending aorta 29 in the retrograde, upstream direction to facilitate insertion through the femoral incision site 31.

The exemplary embodiment of the invention also contemplates variations which facilitate introduction of the instrument shaft 42 through other peripheral vessels, such as the axillary or subclavian artery, wherein the shaft 42 would be formed to have a generally "S"-shaped configuration to follow, in the upstream, retrograde direction, the contour of the centerline of the axillary or subclavian artery, through the left subclavian 39' and to the selected location 38 in the descending aorta. In such a variation, the fluid flow function of the distal and medial ports and their respective relative sizing is reversed. A catheter shaft 42 length of approximately 60-80 centimeters is adequate for such an alternative insertion technique. Other lengths, pre-shaped curvatures and port variations can be established for insertions into other neck, arm, leg or corporeal arterial and venous blood vessels. Such variations in length and pre-shaped curvature are also contemplated by the

present invention for applications requiring open-chest or intercostal approaches which also require minimized incision site size and blood vessel trauma along with managed, segmented CPB and interventional support.

Preferably, the catheter shaft 42 is fabricated to have a thin walled construction to maximize the internal diameter and therefore the flow rate of the fluid communication lumen 44 for a given outside diameter and length of the catheter device 16. The internal diameter is selected to provide the needed fluid flow rate for CPB support while secondary instruments are introduced, manipulated, removed and/or exchanged within the fluid communication lumen 44. The selected internal diameter of the lumen 44 is large enough to support, when such instruments are inserted therethrough, a sufficient minimum CPB flow rate for support of the patient's body. The minimum internal diameter is established based upon the maximum flow rate needed to perfuse cooled, oxygenated blood to the patient to initially induce hypothermia. Once the patient's body tissues have been cooled to the target hypothermic temperature, the maximum flow rate needed is much lower, as previously discussed, due to the lowered demand of tissues for oxygenated blood. Therefore, the maximum flow rate needed after hypothermia has been induced establishes the minimum internal diameter of the fluid communication lumen 44 needed to support the minimum low flow rate of oxygenated blood and other fluids. This minimum internal diameter is increased, if needed, to accommodate the added maximum external diameter, or combination of diameters, of the interventional surgical instrument(s) which are to be introduced through the fluid communication lumen 44. The internal diameter of the lumen 44, or other additional lumens, channels or passageways, may be sized for the introduction of one or more precision engineered second, third or fourth stage instruments including interventional instruments, multi-ballooned, multi-lumen, venting or perfusion catheters, sensors, filter devices, imaging devices, laser, acoustic or electrical energy sources, ablation devices, stents, angioplasty devices, arthrectomy devices and prosthetics.

In a variation of the exemplary embodiment, a portion of the outside circumference of the shaft 42 is formed with a longitudinally extending guide groove or guide key/keyway to accommodate a tongue-in-groove or key-in-keyway relationship with the adjunctive secondary, tertiary or quaternary instruments such that they need not be introduced through a lumen, channel or

passageway of the main stage instrument 10. This variant configuration facilitates the rapid, guided, introduction, removal and exchange of the interventional or sensing instruments through the blood vessel via the single peripheral incision without diminishing the available fluid flow lumen space of the main stage instrument 10.

Thin walled construction of the catheter shaft 42 allows its outside diameter to be minimized in order to reduce the invasiveness of the surgical intervention in the blood vessel and to reduce the trauma at the insertion site 31. The fluid communication lumen 44 may be, for certain CPB applications, configured to allow sufficient blood flow to preserve organ function without hemolysis or other damage to the blood components. For standard cardiopulmonary support techniques, the shaft of the catheter device 16 is constructed to have an outer diameter of 18-24 French size (6-8 millimeters outside diameter) which is sufficient, for a given fluid lumen pressure, to deliver approximately 3-5 liters per minute of oxygenated blood to the patient's body through the distal, medial and downstream fluid ports, 48, 58 and 64, respectively, to preserve the function of the various organ systems and protect against possible ischemic or hypoxic injury.

Although not shown in detail in the drawings and subject to the internal lumen diametrical flow rate and instrument introduction constraints described above, the catheter shaft 42 may, as an alternative to or in conjunction with the relative sizing of the distal, medial and downstream ports, have multiple maximum external and respective minimum internal diameters which progressively decrease from the proximal end 18 to the distal end 20 for a number of reasons. First, assuming for example that a fluid mixture is being perfused to the patient through proximal port 46 and a portion of the fluid flow is perfused through the downstream port 64, then a smaller diameter of tubing can be employed to accommodate the remaining fluid flow. Thus, the minimum internal diameter of the lumen 44 distal to the downstream port 64 may be smaller than the lumen diameter of the fluid communication lumen 44 between this port and the proximal port 46. Similarly, since a portion of the fluid flows through the medial port 58, the minimum internal diameter of the segment of the fluid communication lumen 44 which is distal to the medial port 58 may be further reduced, subject to the minimum diameters needed to support the minimum fluid flow rate required by the heart and the

brain as well as to support the passage of interventional instruments. This multiple diameter construction is accomplished by constructing the shaft 42 to have its maximum diameter over a first segment defined to be that portion of the catheter shaft 42 which is between the external proximal end 18 and the downstream port 64. The diameter transitions to a second, smaller diameter throughout a second segment defined to be that portion of the catheter shaft 42 which is between the downstream port 64 and the medial port 58. The remaining segment would have a still smaller internal diameter between the medial port 58 and the distal port 48. Such reduced internal diameters result in correspondingly smaller external diameters which, in turn, occupy a smaller proportion of the blood vessel lumen space leaving more space available for introduction of adjunctive secondary or other instruments alongside and in parallel with the main stage instrument 10. Further, the smaller internal lumen diameters may also be sized and pre-calibrated such that, for a given fluid pressure at the proximal port 46, fluid is perfused from the respective distal, medial and downstream ports at respective pre-calibrated flow rates. As an alternative to the segment by segment changes in diameter, the fluid communication lumen 44 may also be gradually tapered from its largest diameter at the proximal end 18 to its smallest diameter at the distal port 48.

In variations of the exemplary embodiment, fluid flow control valves may also be incorporated in the catheter device 16 to control the fluid flow through either of the respective ports 48, 58 or through the lumen 44. One such type of optional valve can be comprised by a gauged obturator, shown schematically in FIG. 1 by reference numeral 60 attached to the distal port 48, which can be installed into or adjacent to each of the ports 48, 58 and/or 64 before use of the instrument 10. The gauged obturator 60 is of a fixed-size construction adapted to, upon installation, adjust the effective cross-sectional exit plane area of the respective port to thereby control the maximum rate of flow through the port for a given fluid pressure in the fluid communication lumen 44. A series of gauged obturators may be made available for use with the instrument 10 to facilitate variable relative flow rates for each of the ports, respectively, which may be established on a patient by patient basis and selected by the surgeon prior to introduction of the instrument 10 into the patient. Such obturators would be pre-calibrated to cause an established rate of flow through a given port for the given fluid pressure in the lumen 44. The fixed obturators 60 may be, in an alternative

configuration, independently actuatable and operative to, upon installation, open, partially close or fully close the respective ports 48, 58 and/or 64 in a poppet-type valve configuration. Many of other types of valve component configurations are also possible as outlined below. An actuator shaft (not shown) may be connected to the obturators 60 or other valve components and slidably received in one or more actuator channels 90 and/or 92, formed in the catheter shaft 42, such that the valves may be independently operable from the external location 35.

Other such valves include, but are not limited to, sheath obturators slidable longitudinally or rotatable about the circumference of the shaft 42 to cover the ports, needle valves, poppet valves, sliding or inflatable obturators, port covers, port flaps, actuatable clamps, purse-strings, fluid lumen attenuators, and pressure actuated valves which remain closed until, for example, the lumen 44 is pressurized with fluid to a predetermined valve actuation pressure. Pressure actuated valves may also be included which are responsive to a vacuum such that they only open when the fluid communication lumen 44 has been evacuated to the predetermined valve actuation vacuum or negative pressure. Each of these alternative types of valves may include, among many other possible variations, actuators slidably or rotatably received in the actuator channels 90 and/or 92 of the shaft 42 as schematically illustrated in FIG. 1. All such valve configurations are adaptable for compatibility with introduction of the adjunctive second, third and fourth stage instruments past such valves. Alternatively, such valves may be specifically configured to seal a port or fenestration of the shaft to obturate the opening when not in use by such adjunctive instruments.

Still other variations of the exemplary embodiment include multiple fluid communication lumens which are each dedicated to the respective distal, medial and downstream ports. The size of each of these additional lumens may be individually selected to achieve a particular rate of flow for each of the respective ports. In other alternatives, combinations of lumen sizing, port sizing, use of obturators and/or other types of valves may be selected for a hybrid construction in which any and/or all of such variations may be incorporated into the main stage instrument 10 such that the surgeon has the utmost in flexibility in managing the cardiovascular, cardioneural and corporeal sub-circulations. With such hybrid permutations and combinations of construction, various types of

fluids at various temperatures and viscosities may be simultaneously and independently perfused, irrigated and/or aspirated from any of the ports as needed.

A dual-purpose catheter position stabilizer-flow regulator (hereafter "CPFR") is also shown in FIG. 1 and is mounted to the instrument 10 about the shaft 42 between the distal port 48 and the medial port 58. The CPFR 68 of the exemplary embodiment is an inflatable balloon 68 which, when inflated, atraumatically pushes against the walls of the aortic lumen to stabilize and center the distal end 20 in the aortic lumen 55 to prevent radial displacement of the distal end 20 and also to stabilize the longitudinal position of the instrument 10 in the blood vessel lumen to prevent longitudinal displacement or wandering of the CPFR once it has been advanced to the selected location 38. The inflatable CPFR 68 of this exemplary embodiment is formed about the exterior circumference of the catheter device shaft 15. The interior of the CPFR 68 is in fluid communication with an inflation port formed in the shaft 42 which opens to an inflation lumen extending to the proximal end 18 at the external location 35. The CPFR 68 may be fabricated from many suitable non-toxic, hemocompatible, or non-thrombogenic and non-hemolytic, materials such as a polyurethane known as Tecothane 1080A from Thermedics, Inc., which is thermobonded to the exterior of the shaft circumference and is preshaped to be fully collapsible about the exterior circumference of the shaft 42. Such materials should preferably be optically-clear for the above-described, bubble detecting reasons, although this is not required for all applications. Other suitable balloon materials include, but are not limited to, PET (polyethylene terephthalate) and other types of polyesters, polyethylene, latex, silicone polyvinylchloride, nylon, ethylene vinyl acetate polyester and other polymeric and elastomeric materials. Alternatively, the CPFR material may be fabricated from a non-distensible material and preformed to have a pleated, collapsible shape which is also compatible for introduction, advancement, inflation, collapse and removal. The non-distensible and distensible variations are both adapted to have a maximum outer diameter configured to, when fully inflated, sealingly and atraumatically engage the walls of the blood vessel lumen. The non-distensible variation reaches a maximum inflation configuration having a maximum outer diameter which does not change with a corresponding increase in the inflation pressure. In contrast, although similar in design, the distensible variation reaches a maximum outer diameter at a predetermined inflation

pressure above which, the balloon expands only in the upstream and downstream longitudinal directions. In the exemplary embodiment, the maximum inflated diameter of the CPFR 68 is selected to correspond to the nominal internal diameter of the aortic lumen 55 at the selected location 38. In all variations of the exemplary embodiment, the outer circumferential diameter of the deployed CPFR 68 is preferably sized to engage anatomical aortic structures having average internal, cross-sectional diameters approximately in the range of 1-5 centimeters in diameter and more preferably approximately in the range of 2-3 centimeters, to accommodate the normal human adult range of internal aortic or venous luminal diameters. Smaller and larger diameters are indicated for pediatric patients and for very large patients, respectively.

While in the exemplary embodiment the CPFR 68 is fixed in position relative to the distal end 20, an alternative variation is configured for longitudinal displacement of the CPFR 68 about the exterior of the catheter device 16 by external control. In this variation, the CPFR 68 is connected to the internal end of, for example, an actuator shaft slidably received into a longitudinal channel formed in the exterior circumference of the shaft 42 and extending to the external location 35. Alternatively, the CPFR 68 is mounted to a distal end of a tubular catheter slidably and concentrically formed about the exterior of the catheter device 42. The tubular catheter or the actuator is slidable independently of the catheter device 42 such that the CPFR 68 is longitudinally positionable relative to the catheter device 42. This configuration is adaptable for use with all of the previously and later described embodiments of the main, secondary, tertiary and quaternary stage catheter instruments and CPFRs.

The CPFR 68 also operates as a blood and fluid flow regulator, when partially deployed or inflated, and as a circulation segmenter, flow isolator or blocker, when fully deployed or inflated, which blocks the flow of blood and fluid through the aortic lumen 55 to isolate the cardioneural and cardiovascular sub-circulations from the corporeal or visceral sub-circulation.

The instrument further incorporates a CPFR actuator 72, which in the exemplary embodiment is a balloon lumen 72 that is formed in the catheter device 42. The lumen extends from

the balloon port 70, which is in fluid communication with the interior of the balloon 68, to the external location 35 to terminate in a first connector 72' for communicating a gas or fluid, such as saline, to inflate and deflate the balloon 68. In alternative embodiments of the CPFR, described in more detail below, the actuator 72 is alternatively configured as, for example, an extensor or retractor shaft which is actuatable from the external location 35 for deployment and retraction of the CPFR 68.

A variation of the CPFR 68 of the exemplary embodiment incorporates one of several similar variations of material to achieve a weeping CPFR 68 configuration capable of perfusing a fluid at a predetermined rate of flow for a given inflation pressure. In this variation, either or both the upstream or the downstream surface of the CPFR 68 is formed with a material having a precalibrated porosity with respect to a preestablished maximum inflation pressure and type of perfusate. The perfusate can include a mixture of, for purposes of illustration, blood and other fluids. When inflated, the weeping CPFR 68 configuration is adapted to deliver a precalibrated flow rate of fluid into either or both the upstream or downstream region, with respect to the CPFR 68, of the blood vessel lumen. By way of example, the upstream side of the CPFR 68 is formed from a micro-perforated Tecothane 1080A material. Once the CPFR 68 has been fully inflated with an inflation fluid or perfusate to a predetermined inflation pressure, perfusate passes from within the CPFR to the upstream side at a precalibrated rate of flow. One of the many benefits of this weeping balloon configuration is that its perfusion capability enables the use of the fluid communication lumen of previous embodiments, as an example, for perfusing a second composition or temperature fluid, for irrigating and aspirating fluids and to act as a saline filled, pressure-sensing lumen.

Although optional for the exemplary embodiment, a second inflatable CPFR 74 is shown in FIG. 1 which is positioned such that, when the instrument 10 is inserted into the operative position 26, it may be deployed to further control corporeal or visceral fluid flow through the descending aorta downstream, or in an antegrade direction, to the renal arteries 61. This second CPFR 74 is capable of incorporating all of the variations described above for the first CPFR and preferably configured to, when fully deployed or inflated, atraumatically and sealing engage the walls of the

aortic lumen 55 of the patient at a point downstream of the renal arteries 61. This optional CPFR 74 includes an actuator 76 which in the illustrated embodiment is a second balloon port 78 which is open to a second balloon port 78 in fluid communication with the interior of CPFR 74 and which extends to the external location 35 and terminates in connector 76'.

FIGS. 2a, 2b, 2c and 2d depict enlarged, rotated, partial side views of alternative embodiments of the CPFR discussed above. In these embodiments, a partial view of the main stage instrument is shown generally by reference numeral 100. The CPFR of the previous embodiments has been replaced by the umbrella-shaped CPFR 110 shown in cross-section in each of the figures. The CPFR 110 of this variation operates as a check-valve which is operative to stop or regulate fluid flow in one direction while allowing unobstructed flow in the opposite direction. FIG. 2a shows the CPFR 110 mounted to the catheter device shaft 42 and positioned in the aortic lumen 55 proximate to the selected location 38 discussed above. Fluid flow directional arrows 113 of FIG. 2a reflect retrograde flow past the CPFR which is flowing from the descending aorta 29 to the aortic arch. By manipulation of an actuator at the external location 35, the CPFR 110 may be remotely retracted or collapsed with optional actuators 116. The actuators 116 may be configured to limit the antegrade or deployed deflection of the CPFR 110 to prevent deformation in the antegrade direction or may limit the deflection so as to enable a predetermined antegrade rate of fluid flow past the CPFR 110. This is accomplished by the actuators 116 which are operative to limit the CPFR from extending, in response to antegrade fluid flow, to its fully deployed configuration. When fully deployed, the CPFR 110 is adapted to atraumatically engage the walls of the aortic lumen. In operation, the CPFR 110 does not normally restrict the flow of fluid from a downstream side 123 towards an upstream side 119, in the retrograde flow direction. However, as shown in FIG. 2b, normal antegrade, downstream flow, depicted by fluid flow directional arrows 121, engages the CPFR 110 and thereby passively deploys it into a fluid blocking relationship with the walls of the aortic lumen 55 as shown in FIGS. 2c and 2d. The pressure differential between the upstream side 119 and the downstream side 123 of the CPFR 110 is maintained during surgical interventions when the patient is placed on CPB and fluids are perfused from the distal port 48. Typically, when a patient is placed on CPB, a mixture of temperature controlled fluids and blood is pumped into the patient's aorta through distal

port 48 upstream of the CPFR 110 at a rate of flow sufficient to create the above-described antegrade flow which engages the CPFR, while simultaneously perfusing the arch vessels 39 and the heart vessels. The CPFR 110 may also be deployed by application of a vacuum to the downstream side 123 such as when blood is aspirated from the medial port 58 near the renal arteries 61. This pressure differential of a lower downstream fluid pressure relative to a higher upstream fluid pressure is nominally maintained for a given fluid pressure in the fluid communication lumen 44, since the distal port 48 is larger than the medial port 58 which causes a greater rate of flow to proceed from the distal port 48 which, in turn, creates a higher upstream pressure.

As with the CPFRs of previous embodiments, the CPFR 110 is mounted symmetrically about the catheter device shaft 42 such that when the CPFR 110 deploys, it radially centers the distal end 20 in the aortic lumen 55. Additionally, the surface of the CPFR 110 which contacts the walls of the aortic lumen 55 may be specially shaped or coated to atraumatically engage the intimal blood vessel walls when deployed to prevent longitudinal displacement or movement of the instrument 10 while the fluid pressure differential is maintained. Additional variations to this embodiment may be incorporated wherein the CPFR 110 is formed with stiffeners or reinforced with preshaped materials having shape memory as described above which actively extend the CPFR 110 into the blood vessel lumen 55 as the CPFR actuators 116 are manipulated or as the CPFR 110 is otherwise deployed. Also, additional variations of the CPFR 110 may incorporate an inflatable configuration for active deployment wherein actuators 116 are also modified to act instead as deflection limiters operative to prevent abnormal deflection of the CPFR. A separate inflation lumen would also be incorporated to independently inflate and deflate the variant CPFR(s). Further still, the CPFR 110 may be modified in another alternative variation to incorporate the weeping, pre-calibrated fluid perfusion elements of the previously described CPFRs 68 and 74. Although the exemplary CPFR embodiment described here is generally disposed in a fixed position relative to a distal end 20 of the instrument 10, alternative embodiments may be adapted to incorporate a longitudinally repositionable CPFR analogous in operation to the previously described repositionable CPFR embodiments.

The above-described CPFR variations of the exemplary embodiment may also be configured in other alternative variations to incorporate the blood vessel lumen flow regulating elements described in copending, co-owned U.S. Patent Application serial no. 08/664,361 filed on June 17, 1996 which is hereby incorporated by reference in its entirety.

The various permutations or combinations of the above-described flow control techniques incorporating the previously illustrated ports, lumens, valves and CPFRs of the exemplary embodiment results in a precision engineered main stage catheterization instrument with which the surgeon may control every aspect of sub-circulation segmentation and flow control. This may all be accomplished from a single incision and with a single instrument which affords an efficient means for the surgeon to exercise such control and to modify the parameters of the cardiovascular, cardioneural and corporeal support functions rapidly and without undue burden or uncertainty.

To aid in the precision positioning of the main stage instrument 10 during advancement into the patient's blood vessel, strategically placed sonoreflective, radiopaque and/or high-contrast visual indicia markers 82, which are designed to be visually compatible with a variety of the above-described imaging techniques, may be positioned on the distal end 20 of the instrument 10 to enhance the visibility of the instrument on the visual displays of various types of imaging equipment. The main stage instrument 10 of the present invention may also be used in conjunction with the Bumper and Catheterization Instrument described in co-pending, co-owned U.S. Provisional Patent Applications serial numbers 60/060,158, filed 09/26/97, and 60/073,681, filed 02/04/98, which have previously been incorporated by reference. The bumper instrument described therein may be introduced as a second stage instrument through the fluid communication lumen 44 or through an alternative channel or passageway which may be optionally incorporated into the main stage instrument 10. Alternatively, the main stage instrument 10 may be modified in an alternative embodiment to structurally incorporate the features of the bumper instrument to provide enhanced positioning tactile feedback as described in the 60/060,158 and 60/073,681 applications. While the tactile feedback of the bumper instrument may serve as the primary means for ensuring precision positioning of the main stage instrument 10, the combination of tactile feedback and enhanced visual

registration of the markers 82 on the distal end 20 of the instrument 10 on the visual displays of the imaging and monitoring equipment further improves the surgeon's ability to precisely position the main stage instrument 10. In another variation of the main stage instrument, the catheter shaft 42 and/or the CPFRs may be formed from an optically clear thermoplastic which has been impregnated with a sonoreflective, radiopaque and/or high-contrast visual indicia material which is respectively registrable with each or any of the imaging technologies described above.

Once the main stage catheter instrument 10 has been introduced and is in operation, adjunctive second, third and fourth stage instruments may then be introduced. In surgical interventions directed to selected intracardiac locations or in the coronary arteries, for example, a second stage coronary interventional instrument can be introduced either through the fluid communication lumen 44 of the main stage instrument 10, or alongside in parallel with the main stage instrument 10 through the blood vessel lumen 55, to enable various cardiovascular and cardioneural surgical interventions, including left or right heart interventions. Such adjunctive instruments may also be introduced through separate minimally-invasive percutaneous incisions and/or directly through a central blood vessel wall during open-chest procedures.

In operation with the exemplary embodiment and variations of the present invention, a second stage interventional catheter or instrument is advanced through either the fluid communication lumen 44 of the main stage instrument 10, or through other lumens, channels, or instrument passageways, to the selected location 38 for advancement to a second selected location. As described above the heart must be partially or completely arrested for certain types of cardiac interventions. The exemplary embodiment and all variations and adaptations are compatible for use, however, with a beating, partially arrested and fully arrested heart and for use with many other types of surgical interventions. Before the heart can be arrested, the cardiovascular vasculature must be isolated from the cardioneural vasculature. Once isolated, cardioplegia is perfused to the myocardium in either an antegrade or retrograde procedure. In a retrograde application of cardioplegia, a perfusion catheter is introduced into or proximate to the coronary sinus while a vent catheter is introduced into the aortic root. The exemplary embodiment of the present invention can

be adapted for venous applications to isolate the coronary sinus from the rest of the venous vasculature. In contrast, for antegrade perfusion of cardioplegia, a perfusion catheter is introduced to the aortic root while a vent catheter is introduced to the coronary sinus. In either application, the coronary sinus and/or the aortic root regions must be isolated from the remaining vasculature to restrict the flow of cardioplegia to the myocardium.

Referring now to FIG. 3, a precision engineered secondary catheterization and isolation instrument 150 is shown, for purposes of an illustrative example, which has been introduced through the fluid communication lumen of the main stage instrument 10 to the selected location 38. The secondary instrument 150 is constructed according to the same principles of the exemplary and alternative embodiments and may incorporate any or all of the described variations. For purposes of illustration, the secondary instrument 150 is configured as a fluid communication catheter having an inflatable, balloon-type CPFR 154 similar in construction and operation to the above described embodiments and mounted on the distal extremity of the instrument shaft 156. The secondary instrument 150, as shown in FIG. 3, has been advanced through the aortic arch 41 into the lumen 159 of the ascending aorta 161 with the CPFR 154 positioned and inflated upstream of the brachiocephalic artery 163 and downstream from the coronary arteries 167. The positioning is accomplished through the use of well-known Seldinger needle-guide wire techniques whereby the guide wire is introduced through the main stage instrument 10 and advanced to the desired location in the ascending aorta 159. The secondary instrument 150 also includes a central lumen 170 which opens to a distal fluid flow port 174 at one end and which extends to the external location 35. Once in position with CPFR 154 inflated, the secondary instrument 150 can perfuse, irrigate and aspirate to and from, respectively, the isolated aortic root region. As an example, the secondary instrument can be used to perfuse a mixture of temperature controlled fluid including cooled blood and/or cardioplegia to the coronary arteries 167 to maintain the heart in cardiac arrest while a surgical intervention is to be performed. Additionally, the secondary instrument 150 may incorporate any or all of the flow control valves described above along with an arch perfusion port 176 which is configured to provide additional flow to the arch via a second fluid lumen incorporated into the shaft

178 of instrument 150. To aid in positioning the secondary instrument 150, a marker 172 is schematically represented in FIG. 3 mounted about the distal extremity of the shaft 178.

Also shown in FIG. 3 is a third stage or tertiary bumper instrument 180 similar to that described in U.S. Patent Applications 60/060,158 and 60/073,681. This instrument 180, as shown for illustration purposes, has been deployed through the central lumen 170 of the previous secondary instrument 150 into a position whereby the bumper elements 182 are disposed to correspondingly engage and seat in the cusps of respective aortic valve leaflets thereby biasing the valve leaflets in a closed position as described in more detail in the 60/060,158 and 60/073,681 applications. As can be understood from the preceding description of the invention, the tertiary bumper instrument could also be utilized with the present invention as a second stage bumper instrument whereby it is introduced and advanced into position through the fluid communication lumen 44 of the main stage instrument 10, alongside and in parallel with the secondary instrument 150.

A pigtail left-ventricular vent 190 is also depicted in FIG. 3 and is configured as a fourth stage or quaternary catheter instrument and has been, as shown, introduced through a passageway in the tertiary bumper instrument 180 and advanced across the aortic valve into the left ventricle 193. This quaternary instrument 190 is utilized to drain the left ventricle 193 for multiple purposes including, but not limited to, decompressing the ventricle 193 to unload a failing heart, venting the chamber to create a bloodless surgical field for viewing an intracardiac surgical intervention with remote viewing or sensing equipment and for aspirating regurgitant fluid which has leaked through the aortic valve to prevent distension of the ventricle 193. This instrument 190 may also be configured as a second or third stage instrument wherein it would be introduced through a lumen, channel or passageway in the main or second stage instruments, respectively.

Although not shown in the figures, additional secondary, tertiary and quaternary catheters, devices and instruments are contemplated for use with the main stage catheterization instrument 10. Such additional instruments and devices include, but are not limited to, self-illuminating imaging devices for indirect video or optical angioscopic observations in a bloodless field, such as a vented,

decompressed and drained heart, and for observing intracardiac structures, chambers and defects. The additional imaging devices may also be introduced to the surgical field through a lumen, channel or passageway of other secondary or tertiary catheters, devices or instruments. Such a lumen would be adapted to have an internal diameter which facilitates the passage of such additional instruments and to concurrently support any required communication of fluids therethrough. A fourth stage jet fluid irrigation-infusion catheter and vent can be simultaneously introduced through either the main, second or third stage instruments or devices to clear a bloody field and to aspirate blood and emboli for maintenance of a clear surgical field for intracardiac electrophysiologic interventions, commissurotomies, annuloplasties, thrombectomies, embolectomies, valve declotting procedures and surgical interventions on valves, septal defects and intra-cardiac masses, among many other types of procedures. Many other types of surgical tools and instruments may be similarly configured and introduced. Similar right heart interventions can be performed in the same manner, including thromboendarterectomies or thrombectomies, using the precision engineered main stage catheter instrument of the preferred embodiment in conjunction with various configurations of second, third and fourth stage interventional instruments.

Additional sensors, including acoustic, pressure and chemical composition sensing devices, can be similarly introduced, configured as staged instruments, to monitor the patient's metabolic or blood pressure vital signs. Alternatively, such instruments may be positioned at the external location 35 and be placed in communication with an internal vascular location through a vent lumen or transducer instrument introduced into the vasculature as already described. Further, directed energy devices such as electronic, ultrasonic or laser ablation devices may be similarly configured and introduced to selected intracardiac, cardiovascular or cardioneural surgical intervention sites.

The arrangement of CPFRs on both the main stage catheterization instrument 10 and the other stages can also function, by segmenting the arterial circulation into multiple sub-circulatory regions, to prevent the dispersion of atheromatous, thrombotic or other types of embolic material which has been released into the blood vessel as a result of manipulation of diseased vessels and/or various surgical interventions. Such a function would, in the preferred method, be employed in

conjunction with various types of filter devices configured as secondary or tertiary precision engineered devices or instruments such as a wind-sock type filter, having an embolus aspiration catheter disposed at the cusp of the wind-sock, which could be deployed downstream from a surgical intervention site as an added measure of protection against downstream embolic dispersion. Such a filter instrument would be porous to blood but impermeable to emboli and is disclosed in more detail in copending, co-owned U.S. Provisional Patent Application serial no. 60/060,117 filed on September 26, 1997 which, together with its corresponding utility patent application, is hereby incorporated by reference in its entirety.

One method for using the exemplary embodiment of the precision engineered main stage catheter instrument 10 to institute CPB and cardioplegic arrest of the heart in adults for the purpose of performing various surgical interventions would include:

a. Inserting a precision engineered main stage venous catheter instrument, similar to the embodiment shown in FIG. 1 and described above, into a peripheral femoral vein using guide wire percutaneous insertion techniques. The instrument has a relatively small outer diameter (for adult venous drainage standards) of approximately 20 French, or 6.7 millimeters (hereafter "mm"), and incorporates an elongated tube length of about 80-120 centimeters (hereafter "cm") and includes medial and distal ports with respective lumens extending to an external location. The instrument is advanced from the peripheral incision site to a central venous vessel such as the vena cava and the external ports are connected to the CPB machine for the withdrawal of deoxygenated blood. In the exemplary method, CPFRs of the main stage instruments may be inflated or deployed both above and below the vena cava to isolate the right heart from the rest of the venous vasculature with the medial port therebetween. For retrograde cardioplegia perfusion applications, cardioplegia may be perfused through the medial port. For antegrade cardioplegia perfusion applications, the same would be aspirated from the vena cava.

b. Introducing a guide wire through a fluid communication lumen of the first main stage venous instrument and advancing it past the medial port and through the vena cava and into the

pulmonary artery. Introducing and advancing another precision engineered second stage venous instrument onto the guide wire is accomplished. This second stage vent instrument is configured as a vent catheter and is advanced through a lumen of the first main stage venous catheter instrument, out the medial port and into the pulmonary artery and right heart chambers to augment right heart decompression. This instrument has a small caliber outer diameter of approximately 14 French, or 4.6 mm and is approximately 80-120 mm long. The distal end of this device is formed with a plurality of spaced apart aspiration holes about the outer diameter of the distal end.

c. Inserting a second precision engineered main stage arterial catheterization instrument, of similar construction to that shown in FIGS. 1 and 2 as previously described, into a femoral artery using guide wire percutaneous techniques and advancing it in a retrograde direction into the descending aorta. The second instrument is configured as a variation of the above-described exemplary embodiment as a double-lumen arterial catheterization main stage instrument with distal and medial fluid flow ports, sliding-sheath-type valves and with a relatively small caliber outer diameter (with respect to adult arterial perfusion standards) of approximately 20 French or 6.7 mm and an elongated tube length of approximately 80-120 cm. Two of the second main stage instrument fluid communication lumens are sized to have a minimum internal diameter of nearly 10 French, or 3.3 mm, which combined have an effective luminal diameter of nearly 20 French, or 6.7 mm. The first lumen is in fluid communication with the distal port which is positioned in the descending aortic lumen near to the aortic arch arteries. The second lumen is in fluid communication with a medial port which is located on the elongated tube downstream from the distal port near the renal arteries. The external proximal end of the second main stage instrument is then connected to the CPB machine.

d. Introducing a guide wire through a first of the two fluid communication lumens and advancing it past the distal port and into the ascending aorta until it is just above the aortic valve. Introducing onto the guide wire a second stage instrument configured as a bumper isolator, constructed according to the exemplary embodiment of the 60/060,158 and 60/073,681 applications

and similar in construction to the instrument embodied by FIG. 3, and advancing it to a point just above the aortic valve.

e. Introducing and advancing a third stage instrument, configured as a distally pigtailed, transvalvular left ventricular vent, coaxially into a lumen of the second stage instrument. The vent instrument is advanced past the aortic valve and into the left ventricle, as can be visualized from FIG. 2, to aspirate the left ventricle and decompress the heart. The vent may also be configured as an integrally formed component of the second stage instrument. This instrument is constructed to have an approximately 6 French, or 2 mm, catheter tip formed with a plurality of perfusion-aspiration holes about its distal diameter.

f. Optionally, introducing and advancing various types of sensors configured as second, third or fourth stage instruments, as previously discussed, through the lumens of the first or second main stage or second stage instruments so that the various pressure, oxygen saturation, flow rate, metabolic chemical indicators and other critical variables of the patient may be monitored.

g. Establishing the patient on cardiopulmonary bypass is now accomplished by activating the CPB machine. Typically, the machine includes a blood volume reservoir, a blood heat exchanger, a debubbler, a pump-oxygenator, and reversible, flow-rate-controllable pumps which are activated to establish venous drainage of deoxygenated blood and arterial perfusion of medicated, oxygenated and filtered blood. The blood reservoir receives withdrawn blood which is recycled into the perfusion circulation for return of autologous blood to the patient and also contains a separate reserve chamber for perfusion of exogenous replacement blood or blood components if required. With the instruments connected to the activated CPB machine, arterial perfusion emanates from the distal and medial lumen ports to achieve an approximate rate of blood flow of up to 4-5 liters per minute.

h. Adjusting the CPB heat exchanger to a target temperature of 32 degrees centigrade is performed so the temperature of the perfused arterial blood is lowered to cool the patient's body.

The majority of blood flows out of the medial and distal ports establishing high flow-pressure perfusion until cooling is achieved and cardiac activity is diminished. During the cooling process, antegrade flow through the coronary vessels is achieved as is preferred while retrograde perfusion from the distal port to the aortic arch vessels is performed.

i. Deploying the bumper to render the aortic valve more competent and more closed is done simultaneously as the body is cooled to the target temperature of 32 degrees centigrade. The bumper instrument may be retracted for withdrawal when required. Deploying the CPFR of the second stage bumper instrument to isolate the coronary arteries and the heart from the rest of the vasculature is now accomplished. The first main stage venous instrument CPFRs are deployed to isolate the right heart vasculature.

j. Adjusting the CPB heat exchanger to establish a new target blood temperature of 15 degrees centigrade is done as promptly as possible so that flow through the cerebral lumen is cooled to achieve the coronary and/or cerebral 15 degree target temperatures. Concurrently, cardioplegia and/or cerebroplegia may be infused separately or sequentially to fully arrest cardiac function. As cardioplegia is infused the rate of blood flow from the CPB machine to the body is cut in half thus necessitating continued differential cerebral perfusion. As previously described, lower cerebral flow rates are possible once the brain has been cooled.

k. Venting of the left ventricle of the arrested heart is performed with the left ventricular pigtail vent. If an ultra-low flow rate is established, in the range of 2.0 liters per minute, visualization of the cardiovascular space is then possible by introducing a precision engineered second or third stage imaging instrument through the second main stage fluid communication lumens. Visualization is improved by aspiration- irrigation of the left ventricle with the left ventricle pigtail vent. Such visualization may also be further improved by introduction of the third or fourth stage jet fluid infuser-aspirator instrument described above.

l. Surgical interventions on the patient are now accomplished by introduction of the various other types of main, second, and other stage interventional tools, instruments and catheters described previously.

m. Rewarming the patient, once the surgical procedures are completed, is accomplished by adjusting the heat exchanger so that the target CPB blood temperature is 37 degrees centigrade. As rewarming progresses to the point where the heart begins to beat, the unneeded second, tertiary and quaternary stage instruments, tools and catheters are withdrawn from the various fluid communication lumens to achieve higher-pressure warming flow rates of up to 4-5 liters per minute. Also, the bumper device is retracted from the aortic valve to render it functional as the heart is resuscitated and begins to eject. Additionally, any remaining lumens may be simultaneously perfused with warmed, oxygenated blood to warm the patient more quickly.

n. Reducing cardiopulmonary bypass rates of blood flow, as normal cardiac function resumes, is done by adjusting the flow rates of the CPB pumps and/or by adjusting the valves of the various instruments. Additionally, at this time, the second stage bumper isolator instrument may be partially withdrawn from the aortic root region while perfusion is continued. Once normal, sustained cardiac function is safely reestablished, the CPB machine is deactivated as the various main, second, third and fourth stages instruments are withdrawn.

Many variations in the above-described method are possible. In one such variation of the method, a standard venous drainage catheter may be used in place of the main stage venous catheter instrument for drainage of venous blood from the patient's vena cava and/or right atrium as described in step a and b above. In another variation of the method, cardioneuroplegia is infused through the fluid communication lumen of the main stage arterial catheter instrument or through a second stage catheter instrument into the aortic arch or the ascending aorta in place of the cardioplegia and/or cerebroplegia described in step j. Cardioneuroplegia, or cardiocerebroplegia, is a solution that includes a cardioplegic agent for selectively slowing or stopping the cardiac function and for preserving the myocardium, in addition to one or more neuroplegic and/or

neuroprotective agents for reducing the metabolic demands of the brain and central nervous system and/or for protecting the brain from ischemic or embolic injury. From the aortic arch or the ascending aorta the cardioneuroplegia enters the coronary arteries, as well as the arch vessels and therefore the cerebral circulation. The cardioplegia component of the cardioneuroplegia will be well tolerated by the brain because the blood-brain barrier is left intact and particularly because the neuroplegic component reduces the metabolic demands of the brain. The heart and the brain are thus protected simultaneously. The use of a combined cardioneuroplegic agent also obviates the need for an aortic cross clamp or an intraluminal occluder on the second stage catheter instrument in the ascending aorta to isolate the coronary arteries.

While the present invention has been described herein with respect to the best mode for practicing: an exemplary embodiment, alternative embodiments, variations thereof and a method for using the exemplary embodiment, it will be apparent to one of ordinary skill in the art that many modifications and improvements can be made to the invention without departing from the spirit and scope thereof.

WHAT IS CLAIMED IS:

1. A main stage catheter instrument comprising:

an elongated catheter body configured for introduction into a great vessel in a patient's body, said elongated catheter body having an external proximal end and an internal distal end;

a fluid communication lumen within said elongated catheter body extending from said external proximal end to said internal distal end;

an introduction channel for introducing a second stage catheter or instrument through said elongated catheter body from said external proximal end to said internal distal end;

a first selectively deployable catheter position stabilizer-flow regulator mounted on said elongated catheter body intermediate said external proximal end and said internal distal end, said first selectively deployable catheter position stabilizer-flow regulator being configured, when deployed, to occlude a lumen of the patient's great vessel;

an upstream port communicating with said fluid communication lumen, said upstream port positioned in an upstream direction relative to said first selectively deployable catheter position stabilizer-flow regulator; and

a downstream port communicating with said fluid communication lumen, said downstream port positioned in a downstream direction relative to said first selectively deployable catheter position stabilizer-flow regulator.

2. The main stage catheter instrument of claim 1 wherein said first selectively deployable catheter position stabilizer-flow regulator comprises an inflatable balloon.

3. The main stage catheter instrument of claim 1 wherein said first selectively deployable catheter position stabilizer-flow regulator comprises a selectively deployable external catheter flow control valve.

4. The main stage catheter instrument of claim 1 wherein said first selectively deployable catheter position stabilizer-flow regulator is slidably mounted on said elongated catheter body.

5. The main stage catheter instrument of claim 1 wherein said first selectively deployable catheter position stabilizer-flow regulator is at least partially porous.

6. The main stage catheter instrument of claim 1 wherein said upstream port has an upstream port discharge area and said downstream port has a downstream port discharge area, said upstream port discharge area being greater than said downstream port discharge area.

7. The main stage catheter instrument of claim 1 wherein said introduction channel does not communicate with said fluid communication lumen.

8. The main stage catheter instrument of claim 7 wherein said fluid communication lumen is configured for blood flow at a rate sufficient to maintain the patient's organ systems.

9. The main stage catheter instrument of claim 1 wherein said introduction channel passes through said fluid communication lumen.

10. The main stage catheter instrument of claim 9 wherein said fluid communication lumen is configured for blood flow at a rate sufficient to maintain the patient's organ systems concurrently with introduction of a second stage catheter or instrument through said fluid communication lumen.

11. The main stage catheter instrument of claim 1 wherein said first selectively deployable catheter position stabilizer-flow regulator is positioned on said elongated catheter body such that, when deployed, said first selectively deployable catheter position stabilizer-flow regulator occludes the patient's descending aorta downstream of the patient's aortic arch vessels.

12. The main stage catheter instrument of claim 1 wherein said elongated catheter body is configured for retrograde introduction into the patient's descending aorta and wherein said upstream port is located in the vicinity of said internal distal end and said downstream port is located between said first selectively deployable catheter position stabilizer-flow regulator and said external proximal end.

13. The main stage catheter instrument of claim 12 wherein said elongated catheter body is configured for retrograde introduction into the patient's descending aorta via the patient's femoral artery.

14. The main stage catheter instrument of claim 13 wherein said elongated catheter body is precurved into an approximate J configuration.

15. The main stage catheter instrument of claim 12 wherein said upstream port has an upstream port discharge area and said downstream port has a downstream port discharge area, said upstream port discharge area being greater than said downstream port discharge area.

16. The main stage catheter instrument of claim 12 wherein said fluid communication lumen has a lumen cross sectional area that decreases from said external proximal end to said internal distal end.

17. The main stage catheter instrument of claim 1 wherein said elongated catheter body is configured for antegrade introduction into the patient's descending aorta and wherein said downstream port is located in the vicinity of said internal distal end and said upstream port is located between said first selectively deployable catheter position stabilizer-flow regulator and said external proximal end.

18. The main stage catheter instrument of claim 17 wherein said elongated catheter body is configured for antegrade introduction into the patient's descending aorta via the patient's subclavian artery.

19. The main stage catheter instrument of claim 18 wherein said elongated catheter body is precurved into an approximate S configuration.

20. The main stage catheter instrument of claim 17 wherein said upstream port has an upstream port discharge area and said downstream port has a downstream port discharge area, said upstream port discharge area being greater than said downstream port discharge area.

21. The main stage catheter instrument of claim 1 further comprising:

at least one fluid flow control valve for controlling fluid flow through at least one of said upstream port or said downstream port.

22. The main stage catheter instrument of claim 21 wherein said at least one fluid flow control valve comprises an obturator for selectively controlling fluid flow through at least one of said upstream port or said downstream port.

23. The main stage catheter instrument of claim 1 further comprising:

a hemostasis valve on a proximal end of said introduction channel, said hemostasis valve having a passage therethrough and capable of maintaining a fluidly tight seal upon introduction of a second stage catheter or instrument.

24. The main stage catheter instrument of claim 1 further comprising:

a second selectively deployable catheter position stabilizer-flow regulator mounted on said elongated catheter body intermediate said external proximal end and said internal distal end; and

a medial port communicating with said fluid communication lumen, said medial port positioned between said first selectively deployable catheter position stabilizer-flow regulator and said second selectively deployable catheter position stabilizer-flow regulator.

25. The main stage catheter instrument of claim 24 wherein said second selectively deployable catheter position stabilizer-flow regulator comprises an inflatable balloon.

26. The main stage catheter instrument of claim 24 wherein said second selectively deployable catheter position stabilizer-flow regulator comprises a selectively deployable external catheter flow control valve.

27. The main stage catheter instrument of claim 24 wherein said second selectively deployable catheter position stabilizer-flow regulator is slidably mounted on said elongated catheter body.

28. The main stage catheter instrument of claim 24 wherein said second selectively deployable catheter position stabilizer-flow regulator is at least partially porous.

29. The main stage catheter instrument of claim 24 wherein said upstream port has an upstream port discharge area, said medial port has a medial port discharge area and said downstream port has a downstream port discharge area, said upstream port discharge area being greater than said medial port discharge area, which is greater than said downstream port discharge area.

30. The main stage catheter instrument of claim 24 wherein said introduction channel does not communicate with said fluid communication lumen.

31. The main stage catheter instrument of claim 30 wherein said fluid communication lumen is configured for blood flow at a rate sufficient to maintain the patient's organ systems.

32. The main stage catheter instrument of claim 24 wherein said introduction channel passes through said fluid communication lumen.

33. The main stage catheter instrument of claim 32 wherein said fluid communication lumen is configured for blood flow at a rate sufficient to maintain the patient's organ systems concurrently with introduction of a second stage catheter or instrument through said fluid communication lumen.

34. The main stage catheter instrument of claim 24 wherein said first selectively deployable catheter position stabilizer-flow regulator is positioned on said elongated catheter body such that, when deployed, said first selectively deployable catheter position stabilizer-flow regulator occludes the patient's descending aorta downstream of the patient's aortic arch vessels; and wherein said second selectively deployable catheter position stabilizer-flow regulator is positioned on said elongated catheter body such that, when deployed, said second selectively deployable catheter position stabilizer-flow regulator occludes the patient's descending aorta downstream of the patient's renal arteries.

35. The main stage catheter instrument of claim 24 wherein said elongated catheter body is configured for retrograde introduction into the patient's descending aorta and wherein said upstream port is located in the vicinity of said internal distal end and said downstream port is located between the first and second selectively deployable catheter position stabilizer-flow regulators and said external proximal end.

36. The main stage catheter instrument of claim 35 wherein said elongated catheter body is configured for retrograde introduction into the patient's descending aorta via the patient's femoral artery.

37. The main stage catheter instrument of claim 36 wherein said elongated catheter body is precurved into an approximate J configuration.

38. The main stage catheter instrument of claim 35 wherein said upstream port has an upstream port discharge area, said medial port has a medial port discharge area and said downstream port has a downstream port discharge area, said upstream port discharge area being greater than said medial port discharge area, which is greater than said downstream port discharge area.

39. The main stage catheter instrument of claim 35 wherein said fluid communication lumen has a lumen cross sectional area that decreases from said external proximal end to said internal distal end.

40. The main stage catheter instrument of claim 24 wherein said elongated catheter body is configured for antegrade introduction into the patient's descending aorta and wherein said downstream port is located in the vicinity of said internal distal end and said upstream port is located between the first and second selectively deployable catheter position stabilizer-flow regulators and said external proximal end.

41. The main stage catheter instrument of claim 40 wherein said elongated catheter body is configured for antegrade introduction into the patient's descending aorta via the patient's subclavian artery.

42. The main stage catheter instrument of claim 41 wherein said elongated catheter body is precurved into an approximate S configuration.

43. The main stage catheter instrument of claim 40 wherein said upstream port has an upstream port discharge area, said medial port has a medial port discharge area and said downstream port has a downstream port discharge area, said upstream port discharge area being greater than said medial port discharge area, which is greater than said downstream port discharge area.

44. The main stage catheter instrument of claim 24 further comprising:

at least one fluid flow control valve for controlling fluid flow through at least one of said upstream port, said medial port or said downstream port.

45. The main stage catheter instrument of claim 44 wherein said at least one fluid flow control valve comprises an obturator for selectively controlling fluid flow through at least one of said upstream port, said medial port or said downstream port.

46. The main stage catheter instrument of claim 25 further comprising:

a hemostasis valve on a proximal end of said introduction channel, said hemostasis valve having a passage therethrough and capable of maintaining a fluidly tight seal upon introduction of a second stage catheter or instrument.

47. A multi-stage catheter system comprising:

a second stage arterial catheter instrument having a second elongated catheter body with a proximal end and a distal end; and

a main stage arterial catheter instrument comprising:

an elongated catheter body configured for introduction into a patient's aorta, said elongated catheter body having an external proximal end and an internal distal end, a perfusion blood flow lumen within said elongated catheter body extending from said external proximal end to said internal distal end, an introduction channel for introducing said second stage catheter instrument through said elongated catheter body from said external proximal end to said internal distal end, a first selectively deployable catheter position stabilizer-flow regulator mounted on said elongated catheter body intermediate said external proximal end and said internal distal end, said first selectively deployable catheter position stabilizer-flow regulator being positioned on said elongated catheter body such that, when deployed, said first selectively deployable catheter position stabilizer-flow regulator occludes the patient's descending aorta downstream of the patient's aortic arch vessels, an upstream port positioned on said elongated catheter body in an upstream direction relative to said first selectively deployable catheter position stabilizer-flow regulator, and a

downstream port positioned on said elongated catheter body in a downstream direction relative to said first selectively deployable catheter position stabilizer-flow regulator.

48. The multi-stage catheter system of claim 47 wherein said second stage arterial catheter instrument comprises an occlusion member for occluding the patient's ascending aorta.

49. The multi-stage catheter system of claim 47 wherein said second stage arterial catheter instrument comprises a bumper member for contacting the patient's aortic valve.

50. The multi-stage catheter system of claim 47 further comprising:

a venous cannula having a venous drainage lumen; and

a cardiopulmonary bypass system having an inlet and an outlet, said inlet being connected to said venous drainage lumen of said venous cannula, and said outlet being connected to said perfusion blood flow lumen of said main stage arterial catheter instrument.

51. The multi-stage catheter system of claim 47 wherein said main stage catheter instrument further comprises:

a second selectively deployable catheter position stabilizer-flow regulator mounted on said elongated catheter body intermediate said external proximal end and said internal distal end; and

a medial port positioned on said elongated catheter body between said first selectively deployable catheter position stabilizer-flow regulator and said second selectively deployable catheter position stabilizer-flow regulator.

52. The multi-stage catheter system of claim 51 further comprising:

a venous cannula having a venous drainage lumen; and

a cardiopulmonary bypass system having an inlet and an outlet, said inlet being connected to said venous drainage lumen of said venous cannula, and said outlet being connected to said perfusion blood flow lumen of said main stage arterial catheter instrument.

53. The multi-stage catheter system of claim 51 wherein said second selectively deployable catheter position stabilizer-flow regulator is positioned on said elongated catheter body such that, when deployed, said second selectively deployable catheter position stabilizer-flow regulator occludes the patient's descending aorta downstream of the patient's renal arteries.

54. The multi-stage catheter system of claim 51 wherein said first selectively deployable catheter position stabilizer-flow regulator comprises a first inflatable balloon and said second selectively deployable catheter position stabilizer-flow regulator comprises a second inflatable balloon.

55. The multi-stage catheter system of claim 51 wherein said first selectively deployable catheter position stabilizer-flow regulator comprises a first selectively deployable external catheter flow control valve and said second selectively deployable catheter position stabilizer-flow regulator comprises a second selectively deployable external catheter flow control valve.

56. The multi-stage catheter system of claim 51 wherein said second stage arterial catheter instrument comprises an occlusion member for occluding the patient's ascending aorta.

57. The multi-stage catheter system of claim 56 wherein said occlusion member comprises an inflatable balloon.

58. The multi-stage catheter system of claim 56 wherein said occlusion member comprises a selectively deployable external catheter flow control valve.

59. A method of catheterization comprising:

introducing an elongated catheter body of a main stage arterial catheter instrument into a patient's descending aorta;

occluding the patient's descending aorta downstream of the patient's aortic arch vessels with a first selectively deployable catheter position stabilizer-flow regulator mounted on said elongated catheter body;

occluding the patient's descending aorta downstream of said first selectively deployable catheter position stabilizer-flow regulator with a second selectively deployable catheter position stabilizer-flow regulator mounted on said elongated catheter body;

introducing a second stage catheter instrument through an introduction channel within said elongated catheter body; and

perfusing blood through at least one perfusion lumen within said elongated catheter body and into the patient's aorta upstream of said first selectively deployable catheter position stabilizer-flow regulator through an upstream port, into the patient's aortic between said first selectively deployable catheter position stabilizer-flow regulator and said second selectively deployable catheter position stabilizer-flow regulator through a medial port and into the patient's aorta downstream of said second selectively deployable catheter position stabilizer-flow regulator through a downstream port.

60. The method of catheterization of claim 59 further comprising:

occluding the patient's ascending aorta with an occlusion member mounted on said second stage catheter instrument.

61. The method of catheterization of claim 59 further comprising:

contacting the patient's aortic valve with a bumper member mounted on said second stage catheter instrument.

62. The method of catheterization of claim 59 further comprising:

withdrawing venous blood from the patient through a venous drainage lumen of a venous cannula inserted into one of the patient's veins; and

oxygenating the venous blood and pumping it into the patient through the perfusion lumen.

63. The method of catheterization of claim 62 further comprising: inducing cardioplegic arrest in the patient.

64. The method of catheterization of claim 62 further comprising: infusing a cardioneuroplegic agent in the patient's aorta.

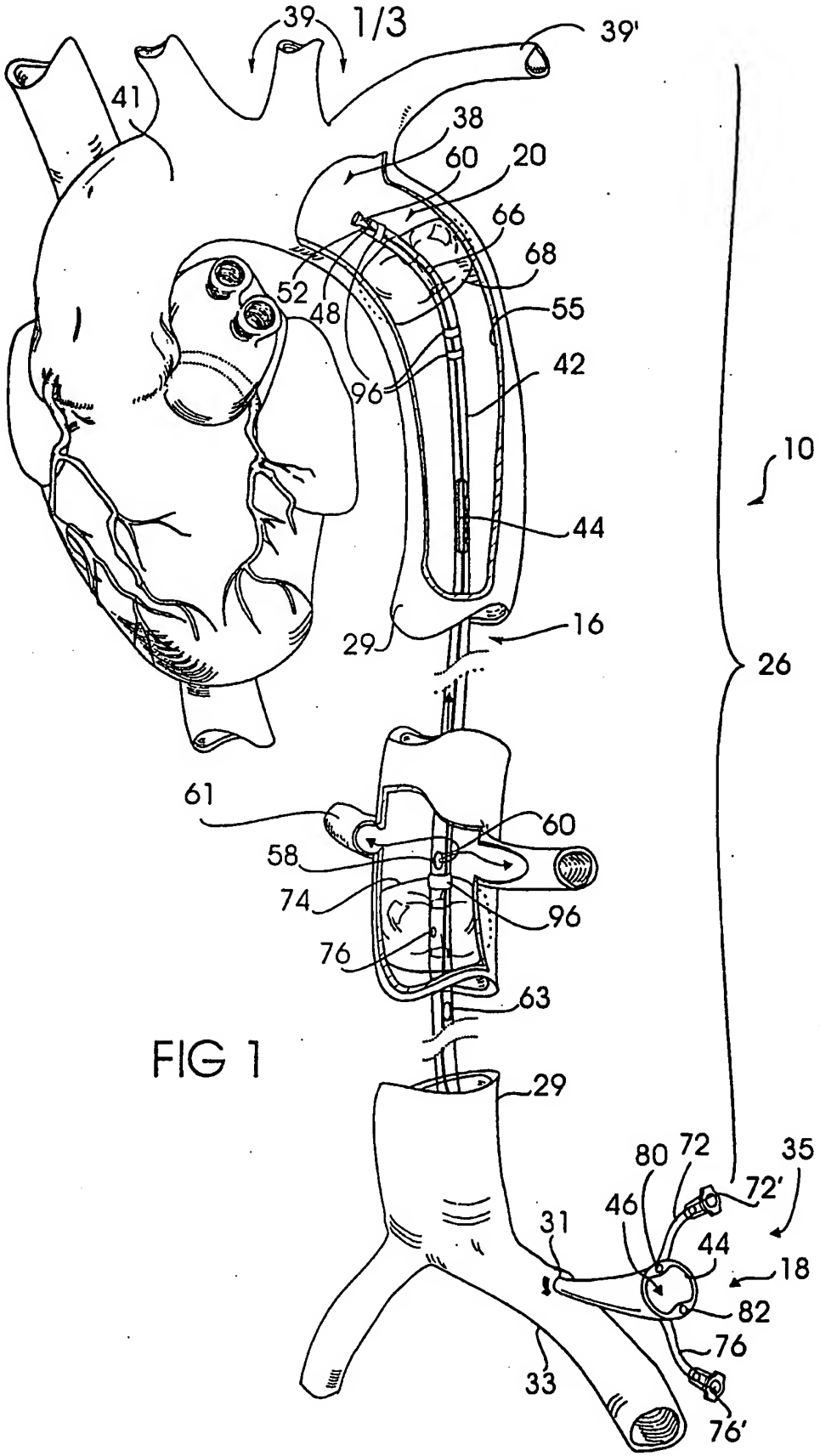
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FIG 1

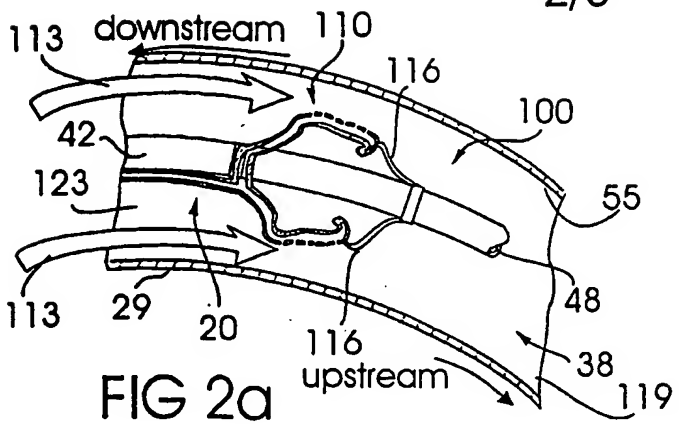

FIG 2a

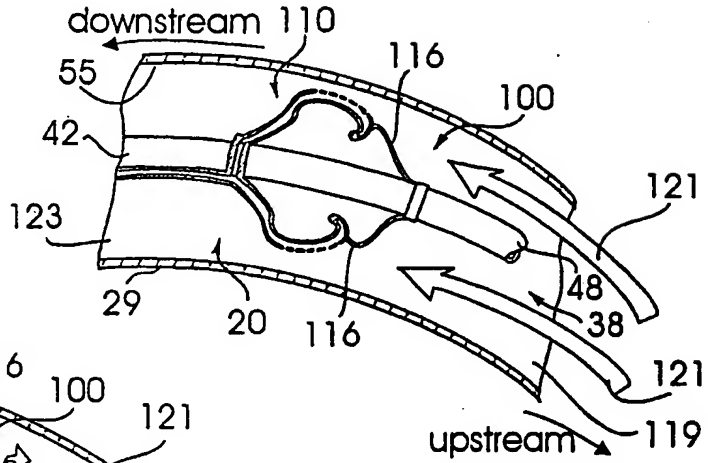

FIG 2b

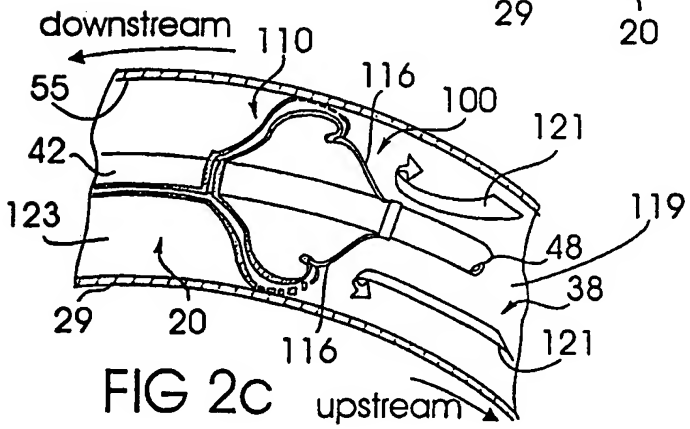

FIG 2c

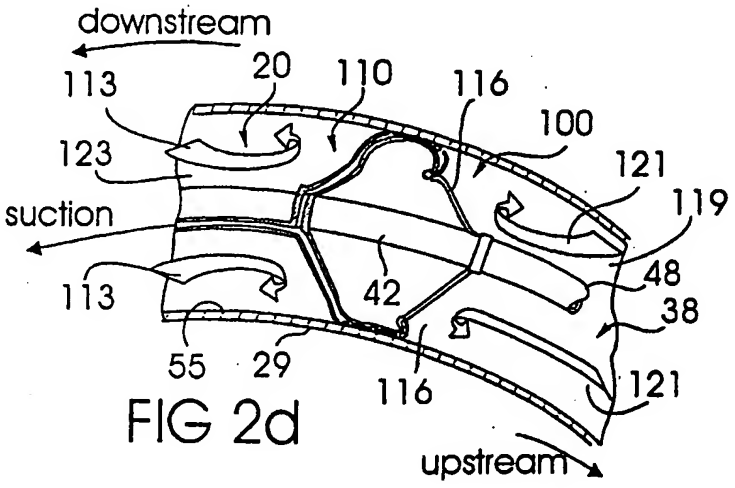

FIG 2d

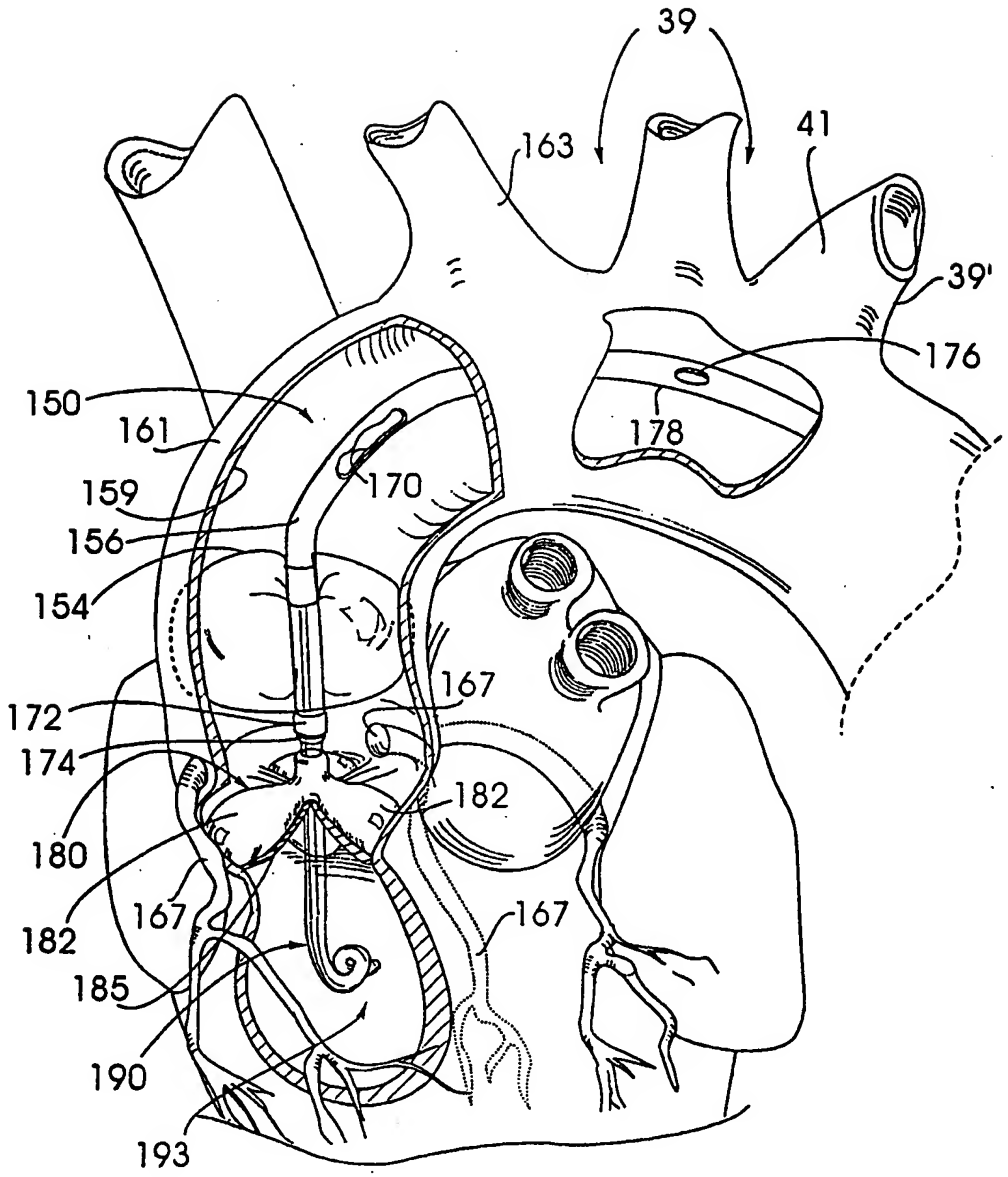
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FIG 3

INTERNATIONAL SEARCH REPORT

Intr ional Application No
PCT/US 98/20165

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M29/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 209 070 A (ABIOMED CARDIOVASCULAR INC.) 21 January 1987 see abstract; claims 1,4-9; figures 1-4	1-56
A	WO 96 40347 A (HEARTPORT INC.) 19 December 1996 see abstract; claims 1,2,5-10; figures 1,2,11,31	1-56
A	US 5 324 260 A (O'NEILL ET AL.) 28 June 1994 see abstract; figures 1-3,6-8	1-56
A	WO 93 25265 A (MALLINCKRODT MEDICAL INC.) 23 December 1993	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 January 1999	15/01/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Michels, N

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

ırnational application No.
PCT/US 98/20165

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 59-64
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intr ional Application No
PCT/US 98/20165

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